

b) analyzing the [DNA] nucleotide sequence determined in step a) for the presence of mutations; and

c) classifying the neoplasia into different subgroups depending on

- (i) the presence or absence of a mutation, and
- (ii) whether the patient is node positive or not[,]; and

d) using the results of [step] steps c)(i) and c(ii) in combination for prognosticating the development of the neoplasia and providing guidance for the treatment of the patient.

2. (Twice Amended) The method of claim 1, wherein a mutation is typed as a mutation selected from the group consisting of a missense mutation, a [or] nonsense mutation, a deletion, [or] and an insertion.

4. (Twice Amended) The method of claim 1 wherein a part or parts [or] of the sequenced gene encode a DNA binding domain.

10. (Twice Amended) The method of claim 1, comprising [one or more of] the following steps:

a) [preparing] obtaining a sample containing genomic DNA or cDNA encoding p53 [,]

b) amplifying the sequences corresponding to the complete coding region of the p53 gene; [at least part of the cancer-related gene,]

c) sequencing the complete coding region sequence obtained in step b); [processing the cancer-related gene with sequencing reactions,] and

d) detecting the products from the sequencing reactions in an automated nucleic acid sequencer, computer software optionally being used to (i) track samples and control process steps and/or (ii) to aid in and/or interpret sequence data obtained.

11. (Twice Amended) A method of detecting mutations in a gene, comprising

a) [preparing] obtaining a sample containing genomic DNA or cDNA encoding p53[,]

b) amplifying the sequences corresponding to the complete coding region of the p53 gene; [at least part of the gene,]

c) sequencing the complete coding region sequence obtained in step b; [processing the amplified DNA to produce sequencing reaction products,]

d) detecting the sequencing reaction products in an automated nucleic acid sequencer to determine a DNA sequence or sequences of the p53 gene[,]

and

e) comparing the sequence or sequences with the corresponding wild type p53 gene sequence or sequences, computer software being used to (i) track samples and control process steps and/or (ii) to aid in interpreting sequence data obtained.

Please add the following new claims.

--14. A method for prognostication of the development of neoplasia and obtaining guidance for treatment in a patient having a neoplasia comprising:

a) determining the nucleotide sequence of the complete coding region of a cancer-related p53 protein from genomic DNA or cDNA derived from a human neoplastic tissue or body fluid;

b) analyzing the nucleotide sequence determined in step a) for the presence of mutations; and

c) classifying the neoplasia into different subgroups depending on

(i) the presence or absence of a mutation, and

(ii) whether the patient is node positive or not; and

d) using the results of steps c)(i) and c)(ii) in combination for prognosticating the development of the neoplasia.

15. A method for prognostication of the development of neoplasia and obtaining guidance for treatment in a patient having a neoplasia comprising:

a) determining the nucleotide sequence of the complete coding region of a cancer-related p53 protein from genomic DNA or cDNA derived from a human neoplastic tissue or body fluid;

b) analyzing the nucleotide sequence determined in step a) for the presence of mutations; and

c) classifying the neoplasia into different subgroups depending on the presence or absence of a mutation; and

d) using the results of steps c) for prognosticating the development of the neoplasia.--

REMARKS

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 2-4, 10 and 11 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite. More specifically, claim 2 has been rejected as being in improper Markush format. Applicants respectfully note that under M.P.E.P. §2173.05(h),II, 'alternative expressions using "or" are acceptable.' As such, claim 2, is presented in acceptable format. However, in the interest of facilitating